In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 21-0523V

TAMELA SPRIGG, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: December 11, 2023

Brian L. Cinelli, Marcus & Cinelli, LLP, Williamsville, NY, for Petitioner.

Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On January 11, 2021, Tamela Sprigg filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that as a result of an influenza ("flu") vaccine received on October 26, 2018, she suffered a left shoulder injury related to vaccine administration ("SIRVA") as defined on the Vaccine Injury Table (the "Table"). Petition (ECF No. 1). For the following reasons, I find that Petitioner more likely than not began to experience left shoulder pain less than forty-eight (48) hours after vaccination, and that she has established all other requirements for a Table SIRVA. Accordingly, she is entitled to compensation.

[1] Because this ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Relevant Procedural History

The Petition was supported by affidavits from Ms. Sprigg and her husband (assigned Exs. 1 – 2), and most of the required medical records (Exs. 3 – 15) (ECF No. 1).[3] The Petition alleged shoulder pain beginning within 48 hours, even though that pain was not documented during medical encounters for other complaints less than 20 days post-vaccination. Petition at ¶¶ 4, 9 - 16.

On December 2, 2021, the case was activated and assigned to OSM's Special Processing Unit ("SPU"), which exists to resolve likely-to-settle claims (ECF No. 13). Petitioner confirmed that her formal treatment course (which included arthroscopic surgery and physical therapy) had concluded (ECF No. 24), and that she had conveyed a demand for past pain and suffering plus past unreimbursable expenses (ECF Nos. 29 – 30). The parties explored settlement from February – July 2023, before reaching an impasse (ECF Nos. 31 – 38). Accordingly, on September 15, 2023, Respondent filed his Rule 4(c) report, in which he opposes compensation of the SIRVA claim on the grounds that there is not preponderant evidence of onset within 48 hours, as required by the Table. Rule 4(c) Report (ECF No. 39) at 6.

Upon reviewing the case file, I have determined that the parties' respective positions regarding onset – and entitlement for the Table SIRVA more generally – are sufficiently developed and therefore ripe for adjudication.

II. Relevant Evidence

I have reviewed all submitted evidence including all medical records, affidavits, the Petition, and the Rule 4(c) Report. I will only summarize or discuss evidence that directly pertain to the determinations herein.

Petitioner was born in 1960. Her pre-vaccination medical history did not include any left shoulder pain, issues, or abnormalities. *See generally* Ex. 16 – 18 (Geisinger Medical Center, including primary care); *see also* Ex 1 (Petitioner's affidavit) at ¶ 4. She pre-scheduled the October 26, 2018, appointment at a Geisinger "flu shot clinic." Ex. 16 at 1221, 1243, 1250. A licensed practical nurse recorded the administration of the vaccine into Petitioner's left deltoid muscle. Ex. 19 at 1.

Fifteen (15) days after vaccination, on November 10, 2018, Petitioner presented to an Evangelical Community Hospital urgent care facility for a sudden onset of left ankle pain rated at 8/10, with no known injury. Ex. 7 at 1. A musculoskeletal exam of the *left*

[3] Additional medical records were filed later as Exs. 16 – 21 (ECF Nos. 8, 22, 27).

ankle documented swelling, tenderness, and pain with weightbearing. *Id.* at 2. An x-ray of the left ankle was unremarkable. *Id.* at 3. Petitioner was instructed to immobilize and rest the ankle, and take acetaminophen or ibuprofen for pain, and follow up if necessary. *Id.* at 2. However, no complaints, exam findings, or assessment of the left shoulder are documented.

A few days later, on November 14, 2018, Petitioner presented to her established primary care provider ("PCP"), Pedro O. Servano, III, M.D., within the Geisinger health system. Ex. 16 at 1291. She reported a one-week history of worsening anxiety, in the context of being "the sole caretaker of a frail and sick mother," for which Dr. Servano recommended taking buspirone twice daily. *Id.* at 1291-92. They also discussed chronic low back pain, for which Dr. Servano said that she could take oxycodone-acetaminophen as needed. Ex. 16 at 1291, 1293. Again, no complaints, exam findings, or assessment of the left shoulder are documented. *Id.*

The next record is from January 4, 2019, when Petitioner secured an appointment with Dr. Servano to address "severe pain in my left shoulder ever since I got a flu shot in October." Ex. 16 at 1318. At the appointment, Dr. Servano observed tenderness at the left acromioclavicular, rotator, and scapulohumeral joints. Ex. 16 at 1304. Dr. Servano felt the complaints were "not related to the shot since there was no deltoid tenderness where the shot was given," *Id.* But he also noted that Petitioner's obesity was an obstacle to the physical exam, and he did not document her range of motion ("ROM"). *Id.* His impression was rotator cuff syndrome and bursitis, for which he prescribed prednisone. *Id.*

Dr. Servano also obtained an MRI on January 17, 2019, and it showed potential subacromial and sub-deltoid bursitis; mild to moderate AC joint osteoarthrosis; and rotator cuff tendinosis. Ex. 16 at 1312-13. The next day, Dr. Servano reviewed the findings and entered a referral to orthopedics. *Id.* at 1329.

At a February 26, 2019, initial evaluation, orthopedist John Furia, M.D., recorded Petitioner's history of left shoulder pain "since October 2018… correlat[ing] to her having flu shot." Ex. 6 at 1. Since that time, her shoulder had been weak and sore, with no improvement despite attempts at rest, activity modification, NSAIDs, and a home exercise program. *Id.* She had pain with lifting, reaching, sleeping, and turning the steering wheel. *Id.* On physical exam of the left shoulder, the findings included mild pain with resisted external rotation; positive Neers and Hawkins test; and tenderness at the level of the subacromial space. *Id.* After reviewing the MRI, Dr. Furia assessed Petitioner with tendinitis, for which he administered a steroid injection and entered a referral to physical therapy ("PT"). *Id.*

At the March 15, 2019, PT initial evaluation, Petitioner reported that her left shoulder pain's onset was on October 26, 2018, and had been caused by the vaccination. Ex. 7 at 4. She denied any prior injuries to her left shoulder. *Id.* The steroid injection had "slightly decreased her pain." *Id.* On exam, she had markedly reduced ROM and weakness. *Id.* at 5. Petitioner was discharged with instructions to use a TENS/NMES unit and to continue her home exercise program. *Id.* at 5 – 6.

A follow-up appointment occurred a few days later (on March 19, 2019), at which time Dr. Furia recorded that Petitioner's left shoulder pain was still painful with lifting, reaching, and sleeping. Ex. 6 at 4. He discussed the options for further treatment. *Id.* Subsequently on April 12, 2019, Petitioner underwent an arthroscopic subacromial decompression, rotator cuff repair, distal clavicle resection, and labral tear debridement performed by Dr. Furia. Ex. 7 at 38 – 40.

At the April 22, 2019, post-operative PT initial evaluation, Petitioner's pain rating was currently 5/10 and ranged from 3 – 9/10. Ex. 7 at 99. The surgical incisions were healing well with no signs of infection. *Id.* at 100. Her active ROM could not be tested, but passive ROM was reduced. *Id.* The therapist planned a course of formal PT sessions twice a week for six weeks, plus use of the TENS unit at home. Ex. 7 at 101; *see also* Ex. 6 at 8-9 (post-operative orthopedics follow-up appointment later that day, noting that Petitioner's use of a sling).

On June 25, 2019, after 14 post-operative PT sessions, Petitioner was discharged. Ex. 7 at 102 - 28. Her pain had decreased to 0/10 currently, and 3/10 at worst. *Id.* at 127. Her ROM was improved to within normal limits, and she had met all goals. *Id.* at 128. She "still ha[d] minor problems with flexibility and strength, but was assured that this will continue to improve over the next several months as long as she continues her HEP." *Id.* at 127.

At a July 1, 2019, follow-up, Petitioner reported that she was "doing great." Ex. 6 at 11. Dr. Furia documented full active and passive ROM and negative Neers and Hawkins tests. *Id.* Dr. Furia assessed that she was "recovered" from her shoulder injury, but she could return if there were any significant problems or concerns. *Id.*

In her January 2021 affidavit, Petitioner recalls that as of October 2018 she was retired and serving as the primary caregiver for her mother and mother-in-law, who both lived in her home. Ex. 1 at ¶ 3. She recalls that the vaccine administrator was standing and she was sitting, and that the vaccine was given higher up on her shoulder than usual. *Id.* at ¶ 5. Upon vaccination, she felt an "immediate achiness," but she hoped that was "just normal soreness," even around the time of her medical encounters for other complaints about two weeks post-vaccination. *Id.* at ¶¶ 6 – 7. She attempted to manage

the pain with Tylenol and ibuprofen. *Id.* at ¶ 8. "After about the third week, when the pain in [her] shoulder seemed to be increasing rather than decreasing, [she] began to suspect that something was wrong," but she was focused on her increasing responsibilities as the primary caregiver for her mother and mother-in-law. *Id.* Eventually, she managed to schedule the January 10, 2019, appointment with her PCP. *Id.* at ¶¶ 9 – 10.

In his own January 2021 affidavit, Petitioner's husband Mark Sprigg recalls that she complained of shoulder pain beginning on the evening of October 26, 2018 – which was memorable, because she "ha[d] a high threshold for pain and never really complained." Ex. 2 at ¶ 5. Mr. Sprigg recalls these events in the context of Petitioner's mother recently moving into their home in September 2018, and his own mother's worsening dementia and Alzheimer's disease around the same time. *Id.* at ¶ 9.

III. Ruling on Entitlement

A. Legal Standards

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[4] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;

[4] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E).

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

B. Analysis

The parties' only dispute is whether Petitioner experienced the onset of left shoulder pain within forty-eight (48) hours after the October 26, 2018, flu vaccination. 42 C.F.R. §§ 100.3(a)(XIV)(B), (c)(10)(ii).

Respondent avers that there is not preponderant evidence of that factual requirement because Petitioner's first memorialized report of left shoulder pain occurred 76 days after vaccination, despite earlier urgent care and PCP encounters focused on other complaints. Rule 4(c) Report at 6. But those encounters happened less than 20 days after the vaccination, when (as maintained in witness statements) Petitioner and her husband hoped that she was experiencing "just normal soreness" that would subside. Petitioner and her husband also allege that caregiving responsibilities and the December holidays help to explain the subsequent delay in treatment. Ex. 1 at ¶¶ 6 – 7; Ex. 2 at ¶¶ 4 – 10.

This explanation is straightforward, and not contradicted by the subsequent medical records – in which the same PCP, and other providers, documented Petitioner's consistent history originating with the vaccination. *See e.g.*, Ex. 16 at 1318; Ex. 6 at 1; Ex. 7 at 4. Additionally, there is not evidence to support an onset either *before* vaccination or at any specific point beyond the Table timeframe.[5] I thus find preponderant evidence that Petitioner's left shoulder pain more likely than not began within 48 hours after the subject vaccination. (At most, the delay in formal recordation of pain might bear on pain and suffering, since it is evidence that Petitioner was able to live with her initial pain.)

[5] For all of these reasons, Petitioner's case is easily distinguishable from the case cited by Respondent. Rule 4(c) Report at 6 (citing *Gruszka v. Sec'y of Health & Hum. Servs.*, No. 18-1736V, 2022 WL 3024777 (Fed. Cl. Spec. Mstr. July 7, 2022) for the proposition that there was "no preponderant evidence of onset within 48 hours partly bases on intervening visits to an orthopedist where Petitioner did not report shoulder pain." In *Gruszka*, Special Master Horner discussed numerous reasons why the petitioner's onset allegation was unpersuasive – including a prior history of shoulder pain, inconsistent later reporting to medical providers, and unpersuasive live testimony. 2022 WL 3024777 at *13 – 17.

Respondent does not raise any other objections to entitlement (*see generally* Rule 4(c) Report), and based on my independent review, I find that Petitioner has preponderantly established all other requirements for a Table SIRVA claim. 42 C.F.R. § 100.3(c)(10)(i, iii – iv). Accordingly, she need not prove causation-in-fact. Section 11(c)(1)(C). I also find that Petitioner has satisfied all other requirements of Section 11(c) including a sufficiently severe injury, and the lack of other award or settlement. Section 11(c)(A), (B), and (D).

Conclusion and Scheduling Order

For the foregoing reasons, **I find that Petitioner has established entitlement and is thus entitled to compensation for a Table SIRVA following the October 26, 2018, flu vaccine.**

Therefore, the case is now formally in the damages phase. The parties are instructed to return to their efforts at informal resolution. I will however note that Petitioner's compensable treatment course included one x-ray, one MRI, one steroid injection, arthroscopic surgery, and PT – however, she achieved significant improvement and was assessed as "recovered" as of July 2019. But the January 2021 Petition did not allege significant ongoing residuals, and it is far from clear that the left shoulder complaints beginning in or around April 2022 (summarized in the Rule 4(c) Report at 4 – 5) should be included in the compensable damages.

Within 45 days, by no later than Friday, January 26, 2024, Petitioner shall file a Joint Status Report updating on the parties' efforts towards informally resolving damages. If the parties have reached an impasse, the status report shall propose a schedule for either sequential or simultaneous briefing of their respective positions on damages.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master